

## **REMARKS**

In the Final Action dated February 18, 2004, Claims 45-62 and 67-70 are pending and currently under consideration.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance or at least in better condition for appeal. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 45-62 and 67-70 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling support.

In the RCE filed on December 11, 2003, Applicants submitted that Westhusin et al. do not teach that there is any major difference in nuclear transfer steps in a cloning procedure. Applicants also submitted that the techniques that are required to accomplish each of these steps vary slightly between species. In the present Action, the Examiner, however, contends that these slight variations affect the success or failure of the cloning protocol. The Examiner alleges that there is no general guideline for determining which modifications, no matter how large or small, are required to come up with a successful cloning protocol for a new species. The Examiner states that the Declaration of July 12, 2003, executed by Dr. Morrison, has been fully considered. Nevertheless, the Examiner alleges that the Declaration shows that culture *in vitro* to the morula/blastocyst stage is required (in rat, mouse, and cow). The Examiner alleges that Claims 45-62 and 67-70 do not require *in vitro* culture to the morula/blastocyst stage. The Examiner further alleges that culture criteria for other species have not been established.

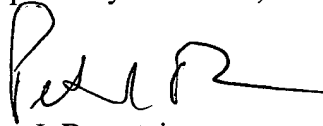
Applicants observe that the Examiner seems to be of the opinion that the disclosure of the present invention is allegedly limited to nuclear transfer technology in rat. In an effort to expedite favorable prosecution, Applicants have canceled Claims 67-70 and amended Claims 45-62 to delineate the nuclear transfer technology in rats. Support for the amendment can be found throughout the specification, e.g., at Examples 1-5 on pages 25-27, and Example 12 on pages 30-31. Applicants reserve the right to file one or more continuing applications directed to the nuclear transfer technology in other non-human species, e.g., mice and cows.

Further, Applicants observe that the Declaration does not state that culture *in vitro* to the morula/blastocyst stage is required for the claimed method. Rather, such *in vitro* experiments were conducted as a means to determine the success of the claimed method, e.g., as exemplified in Example 12 of the specification. See, e.g., Example B attached to Exhibit 1, lines 1-4, of the RCE filed on December 11, 2003. In other words, culture *in vitro* to the morula/blastocyst stage further corroborates the enablement of the present invention. For example, one skilled in the art by following the claimed method, as exemplified, e.g., in Examples 1-5 and 12, is capable of producing a rat embryo, as evidenced by culture *in vitro* to the morula/blastocyst stage of a rat.

Accordingly, Applicants submit that Claims 45-62 and Claims 67-70, as amended, encompass a cloning protocol for rat species. Applicants further submit, as admitted by the Examiner, that the present invention has provided sufficient disclosure, guidance and working examples for one skilled in the art to produce or use a rat embryo.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', with a long horizontal flourish extending to the right.

Peter I. Bernstein  
Registration No. 43,497

Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343  
PIB/ZY:ab